IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ANDREA L. AUCKER, *et al.*,	*	
Plaintiffs,	*	
v.	*	**Civil Action No. RDB-20-0543**
UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION, *et al.*,	*	
Defendants.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

The Plaintiffs in this case are fourteen patients who underwent spinal fusion surgeries performed by the Defendant Dr. Randy Davis using surgical implants. These fourteen individuals and their spouses have brought suit against Defendants University of Maryland Medical System Corporation, Baltimore Washington Medical Center, Inc., Randy Davis, M.D., and RFD Management, LLC, (together "the Defendants") alleging that these healthcare providers violated state tort law by failing to disclose and/or by hiding material information from them before and after they underwent these instrumented spinal fusion operations. (*See* Complaint, ECF No. 2.) The Plaintiffs originally filed their case in the Circuit Court for Baltimore City. (*See* Case No. 24-C-20-000076.) On February 28, 2020, the Defendants sought removal of the case to this Court pursuant to 28 U.S.C. §1441(b), invoking federal question jurisdiction under 28 U.S.C. § 1331. (Notice of Removal, ECF No. 1.) Presently pending before this Court is the Plaintiffs' Motion to Remand (ECF No. 19). The parties'

submissions have been reviewed and no hearing is necessary. *See* Local Rule 105.6 (D. Md. 2018). For the reasons that follow, the Plaintiffs' Motion to Remand (ECF No. 19) is GRANTED. Accordingly, this case will be remanded to the Circuit Court for Baltimore City for further proceedings.

BACKGROUND

The facts contained herein are taken largely from the Plaintiffs' Complaint and are viewed in the Plaintiffs' favor as the Defendants, as removing parties, bear the burden of demonstrating that removal to this Court is proper. *Strawn v. AT&T Mobility, LLC*, 530 F.3d 293, 297 (4th Cir. 2008). The Plaintiffs are fourteen parties (and their spouses) who underwent spinal fusion surgeries at Baltimore Washington Medical Center ("BWMC") performed by Dr. Randy Davis using pedicle screws, screw caps, rods, and cages (together "instrumentation" or "hardware"). (ECF No. 2 ¶¶ 1-21, 62-238.) The instrumentation was provided by non-party Spinal Solutions. (*Id.* ¶¶ 1, 37-42.) The Plaintiffs allege that Dr. Davis received payments from Spinal Solutions in exchange for his use of its instrumentation. (*Id.* ¶¶ 1, 46-49, 246, 257, 267, 293, 300.) They also allege that this fact was not disclosed by him, nor BWMC or the University of Maryland Medical System Corporation ("UMMS"), prior to the Plaintiffs' procedures. (*Id.* ¶¶ 1, 246, 248, 257, 267-68, 300.) Additionally, although the Defendants identified Spinal Solutions as the manufacturer of the relevant instrumentation, the Plaintiffs claim that Spinal Solutions did not in fact manufacture the products and that these products were not approved by the U.S. Food & Drug Administration ("FDA"). (*Id.* ¶¶ 1, 53, 243, 246, 267, 276, 290, 298, 303).

In or around 2005, the Plaintiffs claim that the Defendants received counterfeit copies of devices from Spinal Solutions. (*Id.* ¶¶ 39-42.) Despite the fact that these devices were allegedly devoid of any serial, lot, or catalog numbers, Dr. Davis implanted the hardware in the Plaintiffs, and neither he nor the other Defendants disclosed that these devices lacked FDA approval, were not cleared by the FDA, and were not identifiable. (*Id.* ¶¶ 1, 73-239, 246, 257, 276.) When the Plaintiffs subsequently experienced hardware failures, the devices were either removed or revised. (*Id.* ¶¶ 69-239.) The Defendants allegedly discarded the removed devices without sending them to pathology for examination or making adverse event reports regarding the nature of the device failures. (*Id.* ¶¶ 1, 64-65, 93, 105, 162, 191, 304.) The Plaintiffs further allege that the Defendants continued to use Spinal Solutions instrumentation despite their knowledge of these issues; fraudulently billed the Plaintiffs for Spinal Solutions instrumentation each time these devices were implanted; and arbitrarily billed Plaintiffs different amounts for the same devices. (*Id.* ¶¶ 1, 51, 61, 76-234, 283-85.)

In December of 2019, the fourteen Plaintiffs initiated this action in Maryland's Health Care Alternative Dispute Resolution Office. Pursuant to Maryland law,[1] that Office ordered this case to be transferred to either this Court or the Circuit Court of the appropriate venue. Accordingly, the Plaintiffs' filed their Complaint in the Circuit Court for Baltimore City in January of 2020. They assert a series of claims against the Defendant healthcare providers under Maryland law. Specifically, the Plaintiffs plead lack of informed consent, fraud, intentional infliction of emotional distress, civil conspiracy, violation of the Maryland Consumer Protection Act, and loss of consortium. (*See* ECF No. 2.) On February 28, 2020

[1] Md. Cts. & Jud. Proc. § 3-2A-06B.

the Defendants moved for removal of the case to this Court. (Notice of Removal ¶ 7, ECF No. 1.) The Plaintiffs subsequently moved to remand this case to the Circuit Court for Baltimore City. (Motion to Remand, ECF No. 19.)

STANDARD OF REVIEW

A defendant in a state civil action may remove the case to federal court only if the federal court can exercise original jurisdiction over at least one of the asserted claims. 28 U.S.C. § 1441(a)-(c). Once an action is removed to federal court, the plaintiff may file a motion to remand the case to state court if there is a contention that jurisdiction is defective. 28 U.S.C. § 1447(c). The party seeking removal bears the burden of establishing jurisdiction in the federal court. *Johnson v. Advance America*, 549 F.3d 932, 935 (4th Cir. 2008). On a motion to remand, this Court must "strictly construe the removal statute and resolve all doubts in favor of remanding the case to state court." *Richardson v. Phillip Morris, Inc.*, 950 F. Supp. 700, 701-02 (D. Md. 1997) (citation omitted); *see also Dixon v. Coburg Dairy, Inc.*, 369 F.3d 811, 815-16 (4th Cir. 2004). As this Court has previously noted, this Court is a court of limited jurisdiction. *Mayor & City Council of Baltimore v. BP P.L.C.*, 388 F. Supp. 3d 538, 560 (D. Md. 2019) (as amended June 20, 2019), *aff'd*, 952 F.3d 451 (quoting *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005)).

ANALYSIS

District courts of the United States are courts of limited jurisdiction and possess only the "power authorized by Constitution and statute." *Exxon Mobil Corp.*, 545 U.S. at 552 (citation omitted); *see Home Buyers Warranty Corp. v. Hanna*, 750 F.3d 427, 432 (4th Cir. 2014). They "may not exercise jurisdiction absent a statutory basis . . . ." *Exxon Mobil Corp*, 545 U.S.

at 552. Indeed, a federal court must presume that a case lies outside its limited jurisdiction unless and until jurisdiction has been shown to be proper. *United States v. Poole*, 531 F.3d 263, 274 (4th Cir. 2008) (citing *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)).

Under 28 U.S.C. § 1441, the general removal statute, "any civil action brought in a State court of which the district courts of the United States have original jurisdiction" may be "removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending." 28 U.S.C. § 1441(a). This original jurisdiction includes civil actions that arise under the Constitution, laws, or treaties of the United States. *See* U.S. Const. art. III, § 2 ("The judicial power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made . . . "); *see also* 28 U.S.C. § 1331; *Exxon Mobil Corp.*, 545 U.S. at 552. This is sometimes called federal question jurisdiction, and it provides a federal forum for plaintiffs who seek to vindicate federal rights

The "propriety" of removal on the basis of federal question jurisdiction "depends on whether the claims 'aris[e] under' federal law." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 441 (4th Cir. 2005) (citation omitted). A case "'aris[es] under' federal law in two ways." *Gunn v. Minton*, 568 U.S. 251, 257 (2013); *see Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003). First, and most commonly, "a case arises under federal law when federal law creates the cause of action asserted." *Gunn*, 568 U.S. at 257; *see also Am. Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916) (stating that a "suit arises under the law that creates the cause of action"). Second, a claim is deemed to arise under federal law for purposes of § 1331 when, although it finds its origins in state law, "the plaintiff's right to relief necessarily depends on resolution of

a substantial question of federal law." *Empire HealthChoice Assurance Inc. v. McVeigh*, 547 U.S. 677, 690 (2006); *see Franchise Tax Bd. of State of Cal. v. Constr. Laborers Vacation Tr. for S. Cal.*, 463 U.S. 1, 13 (1983). Therefore, as this Court noted in *Varco v. Tyco Electronics Corporation*, the absence of a federal private right of action is not dispositive. No. RDB-08-1215, 2009 WL 728571, at *4, 5 (D. Md. Mar. 16, 2009).

Yet, as the United States Court of Appeals for the Fourth Circuit explained in *Burrell v. Bayer Corporation*, cases arising under federal law in the absence of a federal cause of action represent a "slim category" of cases. 918 F.3d 372, 379 (4th Cir. 2019). "The 'mere presence of a federal issue in a state cause of action' is not enough to confer jurisdiction." *Id.* (citing *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986)). To determine whether a plaintiff's state law-based claim arises under federal law within the meaning of § 1331, this Court must apply the test derived from the United States Supreme Court's decision in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 313-14 (2005). Under the *Grable* test, federal jurisdiction only exists over a wholly state-law complaint in the limited circumstance where a federal issue is: "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258; *see also Burrell*, 918 F.3d at 379.

The Defendants in this case argue that although the Plaintiffs' causes of action are based in state law, this case falls within this Court's federal question jurisdiction because the claims include allegations that the Defendants improperly implanted them with "non-FDA approved 'adulterated' and 'misbranded' instrumentation" distributed by Spinal Solutions. (ECF No. 1 ¶ 7.) They characterize the Plaintiffs' Complaint as asserting that the Defendants:

> are responsible for the alleged failure of the non-party distributor to obtain FDA approval to assemble FDA-cleared devices into surgical kits and for the alleged failure of that non-party distributor to provide unique identification stickers for each of the dozens of screws, rods, and caps contained in the surgical kit.

(*Id.*) They assert that the FDA through the Federal Food, Drug and Cosmetic Act (the "FDCA"), 21 U.S.C. § 360c, *et seq.*, "has promulgated a comprehensive regulatory scheme governing the design, manufacturing, marketing, and handling of medical devices," and that accordingly, the Plaintiffs' Complaint "at its core" raises a federal question. (*Id.* (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).) Generally, the Defendants argue that although Plaintiffs' claims are purportedly pled under state law, their Complaint is "necessarily predicated on alleged breaches of duties imposed by federal law and challenges the safety and effectiveness of devices that are subject to pervasive federal regulation and administrative oversight." (ECF No. 1 ¶ 10.) However, under *Grable*, this Court lacks jurisdiction to hear the Plaintiffs' case.

First, the Plaintiffs' claims, brought under state law, do not "necessarily raise" federal-law questions. In this case, the Defendants essentially argue that there is federal question jurisdiction because medical devices "sold and distributed in the United States are regulated by the FDA," and that the general interest of "consistency" in the enforcement of these federal rules is sufficient to create jurisdiction. (*See* Notice of Removal ¶¶ 7, 14, 18, ECF No. 1). The Fourth Circuit has squarely rejected this sort of reasoning. In *Burrell*, the Fourth Circuit followed numerous district courts in holding that state-law tort and products liability claims regarding medical devices regulated by the FDA did not give rise to federal question jurisdiction. 918 F.3d at 381. Similarly, in *Pinney*, the plaintiffs alleged violations of state

products liability, consumer protection, fraud, conspiracy, and negligence laws, and the Court rejected the argument that related Federal Communications Commission regulations of cell phones created federal question jurisdiction over the state law claims. 402 F.3d at 442-49. In these cases, the Fourth Circuit made clear that a federal question is "necessarily raised" for purposes of § 1331 only if it is a "necessary element of one of the well-pleaded state claims." *Burrell*, 918 F.3d at 381 (citing *Franchise Tax Bd.*, 463 U.S. at 13). It is not enough that federal law becomes relevant by virtue of a "defense . . . anticipated in the plaintiff's complaint," as is often the case in suits involving heavily-regulated devices. *Franchise Tax Bd.*, 463 U.S. at 14; *see also Pinney*, 402 F.3d at 445-46. The elements of the Plaintiffs' state law claims in this case can each be established without resort to federal law. Thus, any issue of federal law, as in *Burrell* and *Pinney*, is merely "lurking" in the background. *See Burrell*, 918 F.3d at 382 (citing *Pinny*, 402 F.3d at 446).

Second, the Defendants have not shown that the Plaintiffs' Complaint raises questions of federal law that are "substantial" to the federal system as a whole. "[A]s *Grable* makes clear, there is a high bar for treating a federal issue as sufficiently 'substantial' under the third prong of the § 1331 analysis." *Burrell*, 918 F.3d at 385. Indeed, the "classic example" of a substantial question provided by the Supreme Court in *Grable* is "a federal question regarding the constitutionality or construction of a federal statute." *Id.* (citing *Grable*, 545 U.S. at 312-313). As the Supreme Court further explained in *Empire HealthChoice*, substantial questions are ones for which the resolution "would be controlling in numerous other cases." 547 U.S. at 700. In sum, a substantial question will generally involve "a 'pure issue of law,' rather than being 'fact-bound and situation specific.'" *Burrell*, 918 F.3d at 385 (citing *Empire HealthChoice*, 547 U.S. at

700-01). The "crux" of what makes a question "substantial" for purposes of § 1331 is that it is "importan[t] . . . to the federal system as a whole," and not just to the "particular parties in the immediate suit." *Burrell*, 918 F.3d at 385 (citing *Gunn*, 568 U.S. at 260).

In this case, the Defendants allege that the Plaintiffs' claims regarding the application of the FDA's premarket authorization requirements to repackagers would contradict the published guidance of the FDA itself and, therefore, would "dramatically impact" the regulation of an entire industry. (ECF No. 1 ¶¶ 14, 18.) Assuming this is a correct description of one issue in the case at hand, the Plaintiffs' Complaint does not present a "pure issue of law," and instead presents a fact-bound question regarding what was actually done by the relevant repackager, Spinal Solutions. Just as the Fourth Circuit said of the plaintiffs in *Burrell*, the Plaintiffs in this case are not arguing that the FDA's requirements are "unconstitutional" or that "the FDA has exceeded its statutory authority or misapplied its own regulations." 918 F.3d 372. Instead, this case presents numerous dispositive issues unrelated to federal law—the alleged federal issue does not "predominate" those state law and factual issues. *See Varco*, 2009 WL 728571, at *5. The alleged federal issue is simply not substantial within the meaning of *Grable*.

Third, even if this case necessarily raised an issue of federal law, and that issue of federal law were substantial, the Defendants have also failed to show that this case is "capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. As this Court has held, consistent with the exception outlined by *Grable*, the lack of a private federal cause of action is not dispositive of whether a plaintiff's claims may qualify for federal question jurisdiction. *See Varco*, 2009 WL 728571, at *5. However, the

Supreme Court has also made clear that "the combination of no federal cause of action and no preemption of state remedies" is "an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331." *Grable*, 545 U.S. at 318. The Defendants argue that the federal government has an interest in consistency of the application of the Federal Food, Drug, & Cosmetic Act ("FDCA"). (ECF No. 1 ¶ 7.) The FDCA may in some ways be relevant to the claims presented in this case, but it does not provide a private cause of action, nor does it preempt state laws related to the sort of informed consent, fraud, civil conspiracy, or consumer protection claims asserted here. Further, in *Merrell Dow*, the plaintiffs sued a drug manufacturer under various state law product liability theories, alleging that the drug was "misbranded" in violation of the FDCA. 478 U.S. at 805. The Court held that the presence of a federal issue as an element of a state tort did not confer federal question jurisdiction where the FDCA did not provide a private right to action, emphasizing that it would "flout" or "undermine" congressional intent to exercise federal question jurisdiction in that case. *Id.* at 812-13. The argument that there was an alleged federal interest in seeing that the FDCA was interpreted with consistency was unavailing in *Merrell Dow*, and it is unavailing now.

Overall, numerous opinions of the Supreme Court, the Fourth Circuit, and this Court have made clear that state law product liability claims are not subject to removal merely because the FDCA regulates drugs and medical devices. *See Merrell Dow*, 478 U.S. 804; *Burrell*, 918 F.3d 372; *Larson v. Abbott Labs.*, No. ELH-13-0554, 2013 WL 5937824, at *10 (D. Md. Nov. 5, 2013) (holding removal improper where plaintiffs sued a pharmaceutical manufacturer under state product liabilities theories for injuries caused by a drug which allegedly lacked testing required by the FDCA). Similarly, in this case the Plaintiffs are claiming violations of

state law with respect to a failure to comply with FDA regulations. The Plaintiffs' Complaint does not contain any causes of action provided for by federal statute or federal common law. The only connection to federal law is the Plaintiffs' allegation that the Defendants used a device for which the non-party distributor failed to obtain FDA approval. (ECF No. 1 ¶ 7.) The Fourth Circuit in *Burrell* followed the "substantial majority of district courts" which have held "that state-law tort and product liability claims regarding medical devices regulated by the FDA . . . do no give rise to federal question jurisdiction." 918 F.3d at 380. Accordingly, there is no federal question jurisdiction in this case.

CONCLUSION

For the foregoing reasons, the Plaintiffs' Motion to Remand (ECF No. 19) is GRANTED. Accordingly, pursuant to 28 U.S.C. § 1447(c), this case is remanded to the Circuit Court for Baltimore City for further proceedings.

A Separate Order follows.

Dated: December 29, 2020

/s/
Richard D. Bennett
United States District Judge